K001632

510(k) Summary*

JUN 1 9 2000

MEDICAL INSTRUMENTS

(a) (1) **Submitter's name, address**

AVL Scientific Corporation
235 Hembree Park Drive
Roswell, GA 30076

Contact Person

Randy Byrd
Director, Quality Assurance
(770) 576-5000 x 631

Date of preparation of this summary: 25 May 2000

(2) **Device trade or proprietary name:** **OPTI-check PLUS Multi-Analyte Control**

Device common or usual name or classification name:

Multi Analyte Control Solution, All Types (Assayed and Unassayed)

	CLASSIFICATION			
PRODUCT NOMENCLATURE	NUMBER	CLASS	PANEL	
MULTI ANALYTE CONTROL SOLUTION	862.1660	75 JJY	I	CHEMISTRY

(3) **Substantial Equivalence**

AVL **OPTI-check PLUS** is substantially equivalent in function, safety and efficacy to a number of currently marketed devices known as 'Combi' or 'Multi-Analyte' control solutions. In example:

Comparison of OPTI-check PLUS to predicate devices for substantial equivalency

Characteristic	Predicate Devices			Modified Device
Name:	Control for pH, Blood Gases, Electrolytes	COMBI-trol PLUS Multi-Analyte Control	AVL OPTI-check Multi-Analyte Control	OPTI-check PLUS Mult-Analyte Control
510(k), Date:	K833146, 11/28/83	K972868, 08/28/97	K974822, 01/22/98	
Number of levels:	3	3	3	3
Analytes:	pH, PCO_2, PO_2	pH, PCO_2, PO_2, Na^+, K^+, Cl^-, iCa^{++} Li^+, iMg^{++}, tHb, Hb derivatives, Urea, Glucose, Lactate	pH, PCO2, PO2, Na^+, K^+, Cl^-, iCa^{++} tHb, SO_2	pH, PCO_2, PO_2, Na^+, K^+, Cl^-, iCa^{++} tHb, SO_2, Urea, Glucose
Container:	glass ampoule	glass ampoule	glass ampoule	glass ampoule
Fill volume:	1.7 mL	1.7 mL	1.7 mL	1.7 mL
Color:	clear	red	milky	milky
Matrix:	HEPES based aqueous	HEPES based aqueous with dyes to simulate Hb and derivatives	HEPES based aqueous with polystyrene beads to simulate Hb and SO_2	HEPES based aqueous with polystyrene beads to simulate Hb and SO_2

* This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

(4) **Description of the new device**

OPTI-check PLUS is a specially formulated aqueous liquid material intended to for use to monitor all analytes measured by the OPTI Critical Care Analyzer. It contains a stable suspension of polystyrene microbeads which reflect and partially absorb red and infrared light similar to erythrocytes, allowing true simulation of the measurement of tHb and SO_2 in exactly the same manner as these analytes are determined in whole blood by the AVL OPTI Critical Care Analyzer. The three control levels contain three different concentrations of microbeads to simulate low, medium, and high hematocrit blood samples. **OPTI-check PLUS** provides a convenient method of performing periodic QC checks for laboratories selecting to measure liquid QC material as a part of their quality assurance program.

While the product is optimized for performance on the AVL OPTI Critical Care Analyzer, it may be used to monitor the measurement of blood gas, electrolyte values and metabolite values in conventional instrumentation. OPTI-check contains clinically relevant quantities of pH, PCO_2, PO_2, sodium, potassium, ionized calcium, chloride, glucose and urea and suitable concentrations of microbeads to simulate clinically relevant values of tHb and oxygen saturation.

(5) **Intended use of the device**

OPTI-check PLUS assayed control is intended to be used to monitor and evaluate the analytical performance of the AVL OPTI Critical Care Analyzer for the analytes listed in the package insert..

(6) **Technological characteristics of the device.**

OPTI-check PLUS assayed control is intended to be used to monitor and evaluate the analytical performance of the AVL OPTI Critical Care Analyzer for the analytes listed in the package insert is technologically equivalent to currently marketed products to which substantial equivalence is claimed. It contains a low concentration, stable suspension of polystyrene microbeads which reflect and partially absorb red and infrared light similar to erythrocytes, allowing true simulation of the measurement of tHb and SO_2 in exactly the same manner as these analytes are determined in whole blood by the AVL OPTI Critical Care Analyzer.

(b) (1) **Summary of non-clinical tests submitted with the premarket notification for the device.**

Accelerated aging studies on most labile analytes, together with experience with other products with similar formulations support stability claim.

(b) (2) **Summary of clinical tests submitted with the premarket notification for the device.**

N/A

(b) (3) **Conclusions drawn from the clinical and non-clinical trials.**

Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 1 9 2000

Mr. Randy Byrd
Director, Quality Assurance
AVL Scientific Corporation
235 Hembree Park Drive
Roswell, Georgia 30076

Re: K001632
Trade Name: AVL OPTI-check PLUS Multi-Analyte Control
Regulatory Class: II
Product Code: JJY
Dated: May 25, 2000
Received: May 26, 2000

Dear Mr. Byrd:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K001632

Device Name: OPTI-check PLUS Multi-Analyte Control

OPTI-check PLUS assayed control is intended to be used to monitor and evaluate the analytical performance of the AVL OPTI Critical Care Analyzer for the analytes listed in the package insert.

For *In Vitro* Diagnostic Use

Indications for Use

As a part of the quality control program in institutions reporting those analytes listed in the package insert, OPTI-check PLUS Multi-Analyte Control should be used in the AVL OPTI Critical Care Analyzer to evaluate test precision and to detect systematic analytical deviations in those laboratories choosing to use a traditional, liquid, quality control product.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001632

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)